

her “Response to Arguments”: “Appellants arguments filed 4/13/2009 have been fully considered but they are not persuasive.”

Remarks

1. Claim rejections under 35 U.S.C. §103(a)

a. Claims 1, 3, 6-10, 12-15, 18, 19 and 21

Claims 1, 3, 6-10, 12-15, 18, 19 and 21 are rejected under 35 U.S.C. §103(a), allegedly as being unpatentable over Wheeler (WO 97/32559; hereinafter WO’559) in view of the Clariant product brochure (hereinafter “Clariant”) or in view of Beerse *et al.* (US Patent No. 6,294,186; hereinafter US’186). This rejection is respectfully traversed.

The question to be considered, when making a determination as to the obviousness of the present invention under §103(a), is whether one of ordinary skill in the art, at the time the invention was made, could have predicted that substituting the polymeric sulfonic acid gellant taught in Clariant or in US’186 for the conventional gellants described in WO’559, would result in a stable, gelled cosmetic or pharmaceutical composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7, using than about 1 percent surfactant.

Prior to addressing the merits of the rejection, the Applicants wish to restate the nature of the present invention. The problem addressed and solved by the present invention is how to formulate a stable and aesthetically appealing (e.g. clear and creamy) water-based, low pH gel which is cooling, gentle and non-greasy, when applied to the skin, while achieving maximum efficacy of incorporated actives, in particular, actives present as electrolytes, e.g., salts, such as alpha- and/or beta-hydroxy acids. Salts are known to disrupt gel structure and therefore to seriously interfere with the maintenance of a stable, clear gel product, in the absence of significant amounts of surfactants. The present invention provides a product and method which solve the problem posed, yet not solved, by the prior art. The present invention is directed to a composition comprising an oil-containing (preferably, silicone containing) biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant, specifically, an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant, and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition. The present invention further relates to a method of thickening a composition comprising a biliquid foam dispersed in a salt-containing aqueous phase having a pH less than 7, comprising gelling the aqueous phase with a polymeric sulfonic acid gellant which is an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range

of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.

Each of the cited references or combination of references fails to teach or suggest the invention as claimed.

The WO'559 reference

The Examiner's obviousness rejection is based on the WO'559 reference for teaching an oil-based biliquid foam and dispersions of the biliquid foam in an aqueous gel which are suitable for use in the cosmetics and pharmaceutical industries. The biliquid foam *per se* is a dispersion of oil droplets in an aqueous base using a small amount of surfactant. The biliquid foam further may be incorporated into an aqueous phase having a low pH and comprising a gelling agent. The reference fails to teach or suggest the Applicants' invention, including the use of any polymeric sulfonic acid gellant, generally, or an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant, specifically, or the surprising and unexpected advantages of using this particular gellant in a biliquid foam-containing aqueous gel composition, since it does not disclose or suggest a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant, specifically, an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant, and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant.

It is the Examiner's position that the WO'559 reference discloses the Applicants' invention; that is, a stable dispersion comprising a biliquid foam and an aqueous gel, including compositions having a low pH, compositions using low levels of surfactant and compositions containing salts, except for the polymeric sulfonic acid gellant and the "appropriate amount of salt". The Examiner suggests that it would be obvious to those skilled in the art to include an appropriate amount of salt in the compositions, based on the teaching in WO'559 that salts may be included to impart an opacifying or pearlescent quality to the compositions. The Examiner relies on the Clariant reference, or on US'186, for the teaching that any gellant, including a polymeric sulfonic acid gellant, for example, an ammonium poly (acryldimethyltauramide-co-vinylformamide) gellant (i.e., Aristoflex AVC®), may be substituted for the gellants, such as Carbopol, xanthan gum, and so forth, described in WO'559 reference, in an attempt to establish *prima facie* obviousness of the present invention.

Clariant

The Clariant brochure describes the properties of a particular polymeric sulfonic acid gellant, Aristoflex® AVC, and examples of oil-in-water emulsions incorporating the gellant. The reference discloses that Aristoflex® AVC is known in the art for use as a gellant and thickener of an aqueous phase of an oil-in-water emulsion, and that the gellant may be used under low pH conditions. The brochure includes four examples of O/W emulsion compositions containing the Aristoflex® AVC gellant, and 2.0 – 4.0 percent surfactants, by total weight of the composition.

US'186

The Examiner uses this reference for the disclosure that one thickener can be used in place of another, and supposedly, for any purpose. The reference describes antimicrobial compositions comprising a benzoic acid analog and a metal salt, and optionally, thickening agents. A laundry list of thickening agents is disclosed, including the following classes: polysaccharides, polyacrylamide polymers, crosslinked polyacrylate polymers, carboxylic acid polymers, the latter including Carbopol, and “other thickeners” which include Aristoflex AVC and xanthan gum. The reference appears to make no distinction among thickeners.

In paragraph 8, on page 9 of the office action, in her “Response to Arguments”, the Examiner misquotes and/or misinterprets the Applicants’ arguments made in their April 13, 2009, response to the previous office action with regard to US'186. The Examiner states that “applicant argues that because the ‘186 patent makes no distinction among thickening agents, the patent does not recognize the problem that was solved by the instant invention. The examiner disagrees with the applicant that the ‘186 patent must recognize the problem that needed to be solved...” The Applicants did not state or suggest that the “186 patent must recognize the problem that needed to be solved, only that it didn’t, further bolstering the Applicants’ position that the use of one type of gellant, ammonium poly (acryldimethyltauramide-co-vinylformamide, to stably gel a composition having a pH less than 7 and a significant salt content using less than 1 percent by weight of surfactant, was not predictable from the cited references, and therefore nonobvious.]

Combined teachings of the references: WO'559 and Clariant or US'186

The combined teachings of WO'559 and Clariant or US'186 fail to render the present invention obvious because, although one of ordinary skill in the art might have attempted a simple substitution of one known gellant for another, expecting to obtain predictable results (i.e. gelling of the aqueous phase of a biliqid-containing dispersion), the person of ordinary skill in the art could not have predicted that the polymeric sulfonic acid gellant could be used to stably gel the aqueous phase in a biliqid containing aqueous composition, where the aqueous phase has a pH of less than 7 and a significant salt presence, using less than 1 percent by weight of surfactant, based on the total weight of the composition. It is to be

noted that this statement, also provided in the Applicants' response of April 13, 2009, is in direct contrast to the inaccurate statement of the Examiner in her "Response to Arguments", in paragraph 6 on page 7 of the office action, that "Applicant argues that the Wheeler reference, WO 97/32559 publication, fails to teach or suggest applicant's invention of surprising and advantageously unexpected use of the particular gellant in a biliquid composition because Wheeler does not teach composition comprising the particular gellant and that the examiner advanced no basis for suggesting the substitution of ammonium poly(acryldimethyltauramide-co-vinylformamide) for the other gellants/thickening agents of Wheeler."

One skilled in the art, at the time the invention was made, would have expected the presence of salts in the composition to affect the viscosity response of the gellant, and thus to destabilize the gel, in the absence of a significant level of surfactants. See, for example, U.S. Patent No. 6,197,318, issued March 6, 2001, at column 11, line 65-column 14, line 17. As disclosed in the patent, carboxyvinyl polymers, such as Carbopol (used as gellants in the WO'559 reference) are known to demonstrate poor salt tolerance when incorporated into external use compositions containing salts, such that the compositions containing the polymers have poor stability (column 11, line 65 - column 12, line 3 of the patent). It is also disclosed in the patent that, although surfactants had traditionally been used in cosmetic emulsion compositions to provide stability, it was becoming increasingly desirable to limit the amount of surfactants due to safety and environmental considerations (column 13, lines 58-67 of the patent). Additionally, it is discussed (column 14, lines 1-17 of the patent) that although carboxyvinyl polymers were considered for use as surfactant replacements, the poor salt tolerance of the polymers required the presence of a further component, e.g., xyloglucan, in the case of the patent, to impart stability to the composition. It is considered surprising and unexpected; that is, entirely unpredictable, in view of the teachings in the references, and the knowledge of those skilled in the art at the time of the present invention, that the polymeric sulfonic acid gellant would be unaffected by the presence of salts in the composition, such that a stable, smooth, non-pilling gel would result without the need for significant levels of surfactants in the composition. In fact, in example 2 in WO'559, sodium chloride is used, rather than the Carbopol used in all of the other examples, together with a substantial amount of a combination of surfactants. Example 3 contains a combination of sodium chloride with Carbopol, but also a substantial amount of surfactants to stabilize the formulation. In other words, the reference teaches against the combination of Carbopol with high salt in the absence of a substantial amount of surfactants. This strongly suggests that the reference recognizes the incompatibility of Carbopol with high salt unless surfactants are used to provide the necessary stability to the formulation. Clearly, gellants can demonstrate different properties, such as the degree of salt tolerance. Therefore, the Examiner's conclusion, from the disclosure in US'186, that "Since xanthan gum and ARISTOFLEX AVC have been

recognized in the art to be thickening agents, one thickening agent can be used in place of the other to obtain the same gelling of thickening effect” is rebutted.

The Examiner remarks in her “Response to Arguments” on page 11, in the first full paragraph, that WO’559 does not list sodium chloride as a thickening agent, and further elaborates that the viscosities before and after the addition of the salt are not known, and that it cannot be concluded that sodium chloride is a gelling agent. The point the Examiner is attempting to make is not clear to the Applicants. However, it is well-known that sodium chloride has many uses in cosmetic products and is often used as a viscosifying or stabilizing agent. The Applicants merely wished to point out the apparent incompatibility of Carbopol and sodium chloride, as evidenced in example 2 in WO’559, where salt is present and Carbopol is omitted, and in example 3 in WO’559 where salt and Carbopol are combined but require surfactants for stability.

In the Examiner’s “Response to Remarks” in first full paragraph on page 12, it is stated “It is clear that the 6,197,318 patent is concerned with large amounts of the polymer, Carbopol to have poor salt tolerance. However, it is also clear that Wheeler discloses use of other gelling agents in amounts in the range of 0.05 to 20% and more particularly 0.2 to 1% and these amounts do not appear to represent large amounts of polymers and US 6,197,318 did not define what large amount would be.” First, it is not at all clear to the Applicants how the Examiner can state that US 6,197,318 is concerned with large amounts of the polymer and also that the patent does not define large amount. In column 12, in lines 11-14, of the patent, it is disclosed that the amount of xyloglucan used with other gellants is in the range of 0.05-10 wt %. In lines 47-49 of column 12, it is disclosed that the ratio of the xyloglucan to carboxyvinylpolymers (e.g., Carbopol) is 1:10-40:1; thus a wide range of the carboxyvinylpolymers is contemplated for use in combination with the xyloglucan to avoid the consequences of salt intolerance by carboxyvinylpolymers in formulations containing the gellants. The Examiner further states in her “Response to Arguments” in the first full paragraph on page 12 of the office action: “There is no teaching in Wheeler that salts negatively impact the biliquid foams. Thus, the skilled artisan would not be discouraged away from the Wheeler reference.” Again, the point the Examiner is attempting to make is not clear. In any event, if Wheeler does not appreciate that gellants may be salt intolerant, then this further buttresses the Applicants’ position that a low pH, high salt, biliquid containing gelled aqueous formulation, which can be stabilized with less than 1% surfactant, is not predictable from the cited references. The Applicants further fail to understand the Examiner’s statement in “Response to Arguments” in paragraph 9 on page 9 of the present office action, “Pages 9-13 of the remarks deal with supposed negative teaching of US 6,197,318 regarding Carbopols and salts and applicant’s contention that because the examiner used a reference to reject the claims, applicant is also entitled to use a reference that was not used in the rejections to show the composition disclosed in the reference is not tenable.” The Applicants cited US

6,197,318, which was published before the filing date of USSN 09/510,756, from which the present application claims priority, to show that, at the time of the invention, those skilled in the art recognized the difficulty in stabilizing salt containing compositions using Carbopol gellant.

The Examiner objects that the Applicants' use of US 6,197,318 to demonstrate that Carbopol has poor tolerance for salts, does not also demonstrate poor salt tolerance for the other thickeners disclosed in WO'559. The Applicants would urge that it would be unduly burdensome to have to demonstrate a salt intolerance property for a dozen or so other gellants described in WO'559, particularly when all of the examples in the reference employ Carbopol (except for example 2 which utilizes sodium chloride) as a thickening agent. Although, as the Examiner states time and again, a reference is not limited to its examples, the WO'559 reference is non-enabling for the other gellants listed therein. Additionally, the Applicants are entitled to use specific examples to support their position when the Examiner uses specific examples in attempt to support her position that WO'559 discloses low pH compositions, and low surfactant compositions and high salt compositions, such as to render the present invention *prima facie* obvious. The point is that the reference does not recognize that conventional thickeners, such as Carbopol, used in the all of the examples except one where sodium chloride is used alone, are salt sensitive at low pH, and that low pH gels, containing significant amounts of salt, require substantial amounts of surfactant to stabilize them. In view of the knowledge of one skilled in the art concerning the gel destabilizing nature of salts, there would be a lack of motivation to "...use appropriate amount of salt that would be provide desired pearlescence and luster to the gelled composition", based on disclosure in WO'559, as suggested by the Examiner. Because the references do not recognize or address the problem solved by the present invention, and because it cannot be predicted from the references that a polymeric sulfonic acid gellant could provide a stable, gelled, low pH, biliqid-containing aqueous composition using less than 1% surfactants, the combined disclosures of the references do not place the present invention into the possession of those skilled in the art.

The Applicants acknowledge that the WO'559 reference discloses a composition containing a biliqid foam dispersed in an aqueous phase. The reference also discloses low pH formulations, formulations containing salt, and formulations containing low levels of surfactants. Nevertheless, the reference fails to disclose or suggest a biliqid-containing aqueous gel composition having a pH less than 7 and a significant amount of salt which is stabilized with less than 1% surfactant. The only teaching in the reference of such compositions having a pH less than 7 is found in the first three examples. Example 1 is directed to a composition in which the pH of the aqueous phase is 6.5. The composition contains less than 1% of surfactants – polyoxyethylene lauryl ether and lauryl betaine. However, the formulation not only lacks the presence of a polymeric sulfonic acid gellant, but also fails to include an essential feature of the claimed invention: an aqueous phase comprising from about 1 to about 10% salt.

As discussed on pages 1 and 2 of the present specification, the problem in the prior art addressed by the present invention is how to formulate a stable, water-based gel-type composition, while achieving the maximum efficacy of incorporated actives, (e.g., salts) and particularly oil-soluble actives, and maintaining an aesthetically pleasing, i.e. clear and non-pilling, appearance and an aesthetically appealing, i.e., creamy, texture. The problem is compounded since many actives can disrupt gel structure, leading to an unstable product with an unacceptable feel on the skin, even moreso when the actives comprise acids, present as electrolytes. Therefore, even were the gellant in the Example 1 formulation of the WO'559 reference replaced by Aristoflex AVC, taught by Clariant or US'186, the resulting formulation would not be the same as the Applicants' compositions, since the resulting formulation would lack the presence of substantial amounts of electrolytes/salts. The reference fails to teach a low pH, salt-containing formulation which can be stably gelled in the presence of less than 1% surfactant.

Examples 2 and 3 of the reference are directed to conditioning shampoos, having low pH. The formulations each include 3% salt, e.g., NaCl. However, even were the gellant of these formulations replaced by Aristoflex AVC, taught by Clariant or US'186, these formulations also would not meet the limitations of the present claims, which call for less than 1% surfactant. Each of the formulations of reference Examples 2 and 3 contains over 20 weight percent surfactants, including ammonium lauryl sulphate, ammonium lauryl ether sulphate, cocamidopropyl betaine, coconut diethanolamide and cetostearyl alcohol. The amount of the aqueous ammonium lauryl sulphate alone in each of the Example 2 and 3 formulations is 13.5% (33% aqueous solution x 41wt. % of the total composition).

The Examiner continues to point to the disclosure in WO'559, on page 3, in the fourth full paragraph, the Examiner stating that "Wheeler discloses that surfactant *is* [emphasis added by the Applicants] present in amount of from 0.05 to 0.5%. The reference actually discloses that "A surfactant to stabilize the formulation may comprise between 0.05 and 0.5%..., thereof." The Examiner questions how the surfactant amount in the compositions in WO'559 can be higher than the upper limit contemplated on page 3 of the reference. The Examiner continues to disregard the further disclosure in the reference, at page 5, line 27–page 6, line 10, that shampoos and shower gels generally contain 4-18% by weight of a primary surfactant and 2-15% by weight of a coactive surfactant. It is disclosed in particular on page 5, lines 7-10 that, "**It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the invention.**" In fact, it is well known that, particularly in shampoos, surfactants are the primary cleansing agent and that surfactants are selected based on proper detergency without degreasing (cleaning without removing too much oil from the hair), ability to form delicate and rich bubbling, easy rinsing, good finish after washing hair, minimal skin/eye irritation, no damage to hair, low toxicity and good biodegradability. Generally, the higher alcohol type-anion

surfactant provides the proper detergency and forms rich bubbles, and a non-ionic surfactant is added as coadjuvant. Additionally, the proper balance of surfactants provides a shampoo with a slightly acidic pH of about 5.5 - 6.5, since a basic environment weakens the hair by breaking the disulfide bonds in hair keratin. Citric acid is typically used to provide the desired pH. The cuticle of the hair, which is exposed after the sebum is stripped away, is covered with overlapping scales that are smoothed and soothed in a properly acidic environment. Aggravated scales don't overlap nicely, and they make hair look dull and feel rough. They can also snag other raised scales on neighboring shafts, resulting in snarls.

Therefore, Examples 2 and 3, the only disclosure of low pH, salt-containing compositions in the WO'559 reference, fail to disclose or suggest the Applicants' invention. The essential features of the Applicants' claims are a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising 0.01–10% of a polymeric sulfonic acid gellant, which is ammonium poly (acryldimethyltauramide-co-vinylformamide), and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount of 1 - 10%, and the composition comprising less than 1% surfactant. As discussed above, one of ordinary skill in the art, reading the disclosure in the WO'559 reference, at page 6, lines 7-10, together with Examples 2 and 3, would simply not have been led to modify the reference compositions by substituting the gellant used in the present invention for the gellant in the reference compositions and also reducing the total amount of surfactants in the low pH shampoo formulations of examples 2 and 3 in the WO'559 reference, to arrive at the Applicants' invention. Given the state of the art at the time the present invention was made (see U.S. Patent 6,197,318, discussed herein), there would have been no reasonable expectation that a polymeric sulfonic acid gellant, such as that described in Clariant or US'186, would have successfully gelled low pH compositions containing a significant level of salt, such as the shampoo formulations in Examples 2 and 3 of the WO'559 reference, in the absence of substantial amounts of surfactants to stabilize the formulation. The difficulty in gelling a low pH aqueous composition containing a significant level of salt is not at all contemplated by the reference. The only teachings one of ordinary skill in the art could have derived from the WO'559 reference concerning gelling low pH formulations are that, in the absence of salts, very little surfactant will stabilize the composition, while in the presence of salts, a significant amount of surfactant is required to stabilize the composition.

That the WO'559 contemplates low pH compositions which may contain salts in an amount in the range called for by the Applicants' claims, or low pH formulations which may contain very low levels of surfactant, is not sufficient to place the Applicants' invention into the possession of one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 82 USPQ 2d 1385, 1396 (US 2007). Nowhere in the cited

reference is there described or suggested a composition comprising a biliquid foam dispersed in a gelled aqueous medium where the gellant used is a polymeric sulfonic acid, let alone ammonium poly(acryldimethyltauramide-co-vinylformamide, in which the pH of the composition is less than 7, the composition contains about 1-10% salts, and the composition is stabilized with less than about 1% surfactant. In the present invention, the use of the polymeric sulfonic gellant results in advantages, as discussed herein, which are entirely unpredictable from the cited references.

The combined teachings of the references fail to place the claimed invention in the possession of one or ordinary skill in the art, since, while the skilled person might have been led to try the Aristoflex® described in Clariant or US'186 as the gellant in the dispersions in the WO'559 reference, the person of ordinary skill in the art would not have been led to also modify the concentrations of salt and surfactant so as to arrive at the Applicants' invention. It could not have been predicted, by those skilled in the art, that the use or the substitution of the polymeric sulfonic acid gellant, as taught by Clariant or US'186, for the conventional gellants in a low pH formulation, including a significant level of electrolytes, such as Examples 2 or 3 of the WO'559 reference, would have permitted a reduction in the total amount of surfactant used to stabilize the formulation to less than 1%. As noted in the present specification at page 3, line 26—page 4, line 6, the gellants recommended for use in the WO'559 reference perform adequately in non-acidic formulations; however, these gellants are incapable of creating a stable dispersion when the aqueous phase to be gelled contains even low levels of electrolytes (e.g., salts of desired active ingredients) at an acidic pH. The Applicants have previously submitted two Declarations (under 37 CFR 1.132, by inventors Harrison and Matathia-Jacobs) which demonstrate that, under certain conditions, including a pH of less than 7, a salt-containing aqueous phase, and less than 1% surfactants, carbomers (e.g. Carbopol), as well as other gellants recommended by the WO'559 reference, for gelling a biliquid foam-containing aqueous gel composition, do not provide a homogeneous, stable, and aesthetically and commercially acceptable product. On the other hand, it is clear from the Declarations that the use of the polymeric sulfonic acid gellant does not merely result in a superior gelling effect, but in a surprising benefit, e.g., an entirely unpredictable outcome. Any efficacy of the polymeric sulfonic acid gelling agents to stabilize an oil-containing biliquid foam dispersed in a salt-containing aqueous phase having an acidic pH of less than 7, in the absence of significant quantities of surfactants, could not have been predicted by those of ordinary skill in the art from the teachings in the cited references and the knowledge of those of ordinary skill in the art at the time of the invention. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining the teachings in WO'559 and Clariant or US'186. ((*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995). When an applicant demonstrates substantially improved results...and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary.))

In her “Response to Arguments”, on pages 16-18, the Examiner provides certain remarks concerning the 37 CFR §1.132 Declarations submitted earlier in the prosecution of this application. Those remarks are addressed in the following paragraphs.

(a) The Matathia-Jacobs declaration: The Examiner first questions the date the declaration was filed, and the date it was considered, indicating the dates provided in the Applicants’ Appeal Brief submitted on August 1, 2009, were inaccurate. The Applicants have reviewed the file, and confirm that the declaration, executed on August 17, 2001, was first submitted together with a response dated August 27, 2001, to an office action in the parent application, and further that the declaration was first considered in an Advisory Action dated September 19, 2001.

The Examiner further states that the data in paragraph 5 of the declaration do not provide the composition used in the data collection, rather only concentrations of the various gellants tested, and also do not indicate that the compositions tested were in the biliquid form, do not indicate the pH, and do not mention the presence of surfactant, salt and oil. Additionally, the Aristoflex is not used outside the claimed range. Therefore, the Examiner concludes that the data presented are not related to a composition which is commensurate in scope with the claimed composition. The Applicants cannot agree with the Examiner. It is clear from paragraph 4 of the declaration that the compositions tested were “substantially the same as the formulation in Example 1 of the present specification, the variables being the gellant and amounts thereof employed and the acid used being lactobionic acid rather than lactic acid.” The Examiner is referred to page 3, paragraphs [0015] – [0017] of US 2002/0058055. The composition (paragraph [0015]) includes salt (lactobionic acid in water at acidic pH), 60% biliquid foam (paragraph [0017]) and AMPS/VIFA copolymer (Aristoflex). The biliquid foam contains oil and surfactant. Therefore, the data presented is commensurate in scope with the present claims.

(b) The Harrison declaration: The Examiner objects that Formula B, which the Applicants indicate corresponds to a composition of the present invention, contains 0.08% AVC, while the present claims call for an amount of the AVC in the range of from 0.01-10%, and that 0.08% is not representative of the claimed range. However, it appears to the Applicants that 0.08% falls within the range of 0.01-10%. Additionally, the Examiner objects that Formulas A and B include sodium chloride as salt whereas the present claims recite only salt and do not specify sodium chloride. The Examiner’s objections are not understood by the Applicants. The Examiner further objects that Formula A, representative of a Wheeler composition, uses in sequence 6-20, water and sodium hydroxide as compared with only water used in Formula B. However, the Examiner is referred to Example 5 in Wheeler, which refers back to Example 4, in which it is indicated that sodium hydroxide is required to disperse the Carbopol. Therefore, this objection by the Examiner also is not understood by the Applicants. The Examiner concludes that “On the whole the composition or formula B from which the data is generated is not commensurate with

the scope of claim 1 making the declaration non-commensurate with the scope of the claims.” But, then the Examiner follows with the statement “Thus with respect to the declaration by James T. Harris [sic], applicant may claim formula B of Appendix A, the composition applicant/declarant shows to produce the unexpected result.” Again, it is not clear what is intended by the Examiner.

b. Claims 1, 3-10, 12-16, 18, 19 and 21

Claims 1, 3-10, 12-16, 18, 19 and 21 are rejected under 35 U.S.C. §103(a), allegedly as being unpatentable over WO'559 in view of US'186 and further in view of Vatter *et al.*, U.S. Patent No. 6,224,888 (hereinafter “US'888”) or France *et al.*, US Patent No. 4,184,978 (hereinafter “US'978”) for reasons of record. This rejection is respectfully traversed.

WO'559 and US'186 are discussed above. The Examiner considers the teaching in WO'559, as modified by the teaching in US'186 to disclose the present invention except for the salts, e.g., the alpha- and beta- hydroxy acids, recited in present claims 4, 5 and 16. For this disclosure, the Examiner relies on US'888 and US'978.

US'888

The reference is concerned with a method of improving the skin penetration of vitamin B₃ compounds from a cosmetic composition. The composition may optionally include skin care actives, and the reference discloses a laundry list of such actives, including moisturizers, for example, alpha-hydroxy acids. It is the Examiner’s position that one having ordinary skill in the art would have had a reasonable expectation of success that adding the moisturizers, such as the salts of lactic acid, to the compositions of WO'559, as modified by Clariant or US'186, would effectively aid in moisturizing and conditioning the skin and hair. The combination of WO'559 and US'186 fails to teach the present invention, since it does not teach, explicitly or implicitly, essential features of the invention which are: a biliquid foam dispersed in an aqueous phase and gelled with ammonium poly(acryldimethyltauramide-co-vinylformamide), including:

- the aqueous phase having a pH less than 7, and
- the aqueous phase including 1-10% salt, and
- the composition comprising less than 1% surfactant.

US'888 too fails to recognize the problem solved by the present invention which is how to formulate a stable and aesthetically appealing (e.g. clear and creamy) water-based, low pH gel, while achieving maximum efficacy of incorporated actives, in particular, actives present as electrolytes, e.g., salts, which are known to disrupt gel structure and therefore seriously interfere with the maintenance of a stable, clear gel product, in the absence of significant amounts of surfactant, and therefore, in contrast to the position of the Examiner, cannot cure the deficiencies in WO'559 and US'888.

US'978

This reference describes water-in-oil emulsion systems for cosmetic and pharmaceutical use which are stabilized by a unique combination of emulsifiers, including certain acyl lactylates, the efficacy of which is said to be attributable in part to the fact that lactic acid and its salts are found naturally in the skin and maintain skin's moisturization. Therefore, in contrast to the position held by the Examiner, US'978 fails to cure the deficiencies of the teachings of WO'559 and US'186 for the same reason given above with respect to US'888.

The Examiner raises no further arguments concerning this rejection in her "Response to Arguments" on pages 19 and 20 of the office action which have not been addressed above by the Applicants.

For all of the above reasons, the Applicants would urge that the Examiner has not established *prima facie* obviousness of the present invention, and it respectfully requested that the claim rejections be withdrawn.

Conclusion

WO'559 discloses low pH formulations of biliquid foam dispersed in a gelled aqueous phase, which may be stabilized with less than 1% surfactant. The reference also discloses formulations containing salt in combination with significant quantities of surfactants. The reference further teaches that various gellants may be used in its formulations. However, WO'559 does not disclose a biliquid foam dispersed in an aqueous phase and gelled with ammonium poly (acryldimethyltauramide-co-vinylformamide) gellant, and including:

- the aqueous phase having a pH less than 7, and
- the aqueous phase including 1-10% salt, and
- the composition comprising less than 1% surfactant.

The Clariant brochure and US'186 disclose a polymeric sulfonic acid gellant, ammonium poly (acryldimethyltauramide-co-vinylformamide), useful in gelling a low pH aqueous phase of an emulsion.

Nevertheless, nowhere in the references is the difficulty in gelling a low pH, salt-containing aqueous phase of a dispersion contemplated, nor is there any disclosure in the references which would have suggested to one of ordinary skill in the art that a polymeric sulfonic acid gelling agent would be efficacious in gelling an oil-containing biliquid foam dispersed in an aqueous phase having an acidic pH of less than 7, and containing significant amounts of electrolytes (e.g., salts), in the absence of significant quantities of surfactants to provide the required stability. Such an unexpected and surprising benefit could not have been predicted by those of ordinary skill in the art from the teachings in the cited references and their knowledge at the time of the invention. The unexpected results unequivocally rebut any *prima facie*

case of obviousness that may be found in combining the teachings in WO'559 and the Clariant brochure or US'186. US'888 and US'978 disclose the use of alpha hydroxy acids in cosmetic compositions for the purpose of delivering moisturization to skin; however there is nothing in these references to cure the deficiencies in the combined teachings of WO'559 and Clariant or US'186.

In light of the amendments and the arguments presented herein, the §103(a) rejections of claims 1, 3, 6-10, 12-15, 18, 19 and 21, based on the disclosure in WO'559 in view of the teachings in Clariant or US'186, and the §103(a) rejections of claims 1, 3-10, 12-16, 18, 19 and 21, based on the disclosure in WO'559 in view of the teachings in Clariant or US'186, and further in view of the disclosures in US'888 or US'978, should be withdrawn as they are unfounded.

The present claims are considered to be in condition for allowance, and prompt issuance of a Notice of allowance is respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

A petition and the requisite fee for extension of time for one month are being submitted concurrently with this paper.

Respectfully submitted,



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Date: December 23, 2009